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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1616

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,401

Applicant(s)

POLLAK ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-44 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 33-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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ACKNOWLEDGE

1. The Examiner acknowledges receipt of amendment 3/12/04 wherein claims 4, 7, 8, 11-13, 26, and 38 were amended; claim 32 was canceled; and claims 43 and 44 were withdrawn.

Note: Claim 1-31 and 33-44 are pending.

WITHDRAWN CLAIMS

2. Claims 43 and 44 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

3. The Applicant's arguments filed 3/12/04 to the rejection of claims 1-13, 19-21, 24, 26-39, 41, and 42 made by the Examiner under 35 USC 112 and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below.

Double Patenting Rejection

The double patenting rejections are WITHDRAWN for reasons of record in Applicant's response.

112 Second Paragraph Rejections

The rejection of claims 1, 2, 4, 7-13, 26-31, 33, 34, 38, 41, and 42 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is

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MAINTAINED for reasons of record in the office action below (see 112 first and second paragraph rejection below) and those of record in the office action mailed 11/21/03.

NEW GROUNDS OF REJECTION

112 First Paragraph Rejection (Written Description)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 4, 6-13, 16, 26, 27, 33, 35, 38, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, the specification lacks written description for the following terms/phrases. **Claim 4**: 'organic molecule having a molecule weight less than about 600 Daltons'. **Claim 6**: 'small organic molecule'. **Claim 7**: 'cysteine amino acid residue derivative'; 'a thiol or thioester group attached to an organic molecule'; 'an amino acid residue derivative including phosphorous and phosphorous containing organic molecule'; and 'accessory group'. **Claim 8**: 'an organic molecule having a molecular weight less than about 600 Daltons'. **Claim 9**: 'NxS4-x ligand derivative' and

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'polyamino polysulfide derivative'. **Claim 10**: 'an organic molecule' and 'derivatives'.

Claim 11: 'an organic molecule having a molecular weight less than about 600

Daltons'; 'an enzyme substrate'; and 'an inhibitor'. **Claim 12**: 'an organic molecule

having a molecular weight less than 600 Daltons'. **Claim 13**: 'an organic molecule

having a molecular weight less than about 600 Daltons'. **Claim 26**: 'an oncological, neurological, inflammatory, infection, and degenerative disease, disorder, or abnormal physical state. **Claim 27**: 'a disease, disorder, or abnormal physical state'. **Claim 33**:

'a disease, disorder, or abnormal physical state'. **Claim 38**: 'cysteine amino acid

derivative'; 'a thiol or thioester group attached to an organic molecule having a

molecular weight less than about 600 Daltons'; 'amino acid residue derivative including

phosphorous and a phosphorous containing organic molecule'; and 'accessory group'.

Claim 41: 'a polypeptide or a polypeptide mimetic of about 3-50 amino acid residues or derivatives thereof'.

Note: Independent claim 1 is rejected because some of the dependent claims cited above read on claim 1.

The terms set forth above fail to satisfy the written description requirement since the specification describes the desired function/property of the composition components, but does not identify any specific composition components or evidence that any such composition components are known/envisioned at the time the invention was made. Thus, since some aspects of the instant invention (below is a discussion regarding the portions of the invention that meet the written description requirement) do not identify composition components useful with the instant invention or provide

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evidence that such components are known, Applicant has not met the written description requirement. Likewise, the methods of using the composition components also do not meet the written description requirements. Furthermore, it is noted that evidence is not of record of indicate that those skilled in the art can identify composition components (and uses thereof) because of the specification's vague functional (and property characteristic) description. In addition, it is noted that in order to make and use the instant invention, trial and error research is necessary. In other words, a person of ordinary skill in the art would be forced to engage in undue experimentation, with no assurance of success, in order to make and use the invention.

The aspects of Applicant's invention which meet the written description requirement are as set forth below. Compositions comprising a metal support surface and conjugate comprising a ligand and target molecule wherein (a) the metal support surface is selected from a cysteine amino acid residue and an amino acid (Note: written description is lacking for a thiol or thioester group attached to an organic molecule and an amino acid derivative including a phosphorus and an phosphorous containing organic molecule for reasons set forth above); (b) the ligands which incorporate three accessory groups selected from (b1) a nitrogen atom, an oxygen atom, or a sulfur atom incorporated in an amino acid residue; (b2) a nitrogen atom, an oxygen atom, a selenium atom, a phosphorus atom, or sulfur atom incorporated into an amino acid residue (Note: written description is lacking for a residue derivative since it is unclear from specification what derivatives (compounds) Applicant is referring to); and (b3) combinations of (b1) and (b2) [Note: it should be noted that written description is

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lacking for ligands with a nitrogen atom, an oxygen atom, a selenium atom, a phosphorous atom, or a sulfur atom incorporated in an organic molecule since written description is lacking for organic molecules that are encompassed by the instant invention for reasons set forth above]; and (c) the targeting molecule is selected from a polypeptide, a peptide (linear and cyclic), a nucleic acid, an oligosaccharide, a steroid, and a peptide or polypeptide mimetic (**Note**: written description is lacking for an organic molecule as set forth above).

112 Second Paragraph Rejection

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-31 and 33-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because of the terms/phrases below. In particular, the terms/phrases are confusing because it is not clear what composition components and uses thereof the claims are directed to. Thus, Applicant is respectfully requested to clarify the terms/phrases and point to page(s) and line number(s) where support may be found for the terms/phrases. **Claim 4**: 'organic molecule having a molecule weight less than about 600 Daltons'. **Claim 6**: 'small organic molecule'. **Claim 7**: 'cysteine amino acid residue derivative'; 'a thiol or thioester group attached to an organic molecule'; 'an amino acid residue derivative including phosphorous and

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phosphorous containing organic molecule'; and 'accessory group'. **Claim 8**: 'an organic molecule having a molecular weight less than about 600 Daltons'. **Claim 9**: 'NxS4-x ligand derivative' and 'polyamino polysulfide derivative'. What is x? What derivatives is Applicant claiming? **Claim 10**: 'an organic molecule' and 'derivatives'. **Claim 11**: 'an organic molecule having a molecular weight less than about 600 Daltons'; 'an enzyme substrate'; and 'an inhibitor'. **Claim 12**: 'an organic molecule having a molecular weight less than 600 Daltons'. **Claim 13**: 'an organic molecule having a molecular weight less than about 600 Daltons'. Claim 16: The sentence as written is incomplete. Applicant is claiming a composition of what? **Claim 26**: 'an oncological, neurological, inflammatory, infection, and degenerative disease, disorder, or abnormal physical state. **Claim 27**: 'a disease, disorder, or abnormal physical state'. **Claim 33**: 'a disease, disorder, or abnormal physical state'. **Claim 38**: 'cysteine amino acid derivative'; 'a thiol or thioester group attached to an organic molecule having a molecular weight less than about 600 Daltons'; 'amino acid residue derivative including phosphorous and a phosphorous containing organic molecule'; and 'accessory group'. **Claim 41**: 'a polypeptide or a polypeptide mimetic of about 3-50 amino acid residues or derivatives thereof'.

Note: Independent claim 1 is rejected because some of the dependent claims cited above read on claim 1. Furthermore, claims depending upon independent claims 1, 35, and 41 are also indefinite.

The terms/phrases are ambiguous because it is unclear what derivatives Applicant's are referring to. What organic molecules Applicant is claiming to be

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compatible with the instant invention. What accessory groups or derivatives thereof Applicant is claiming. What specific diseases, disorders, or conditions Applicant is claiming.

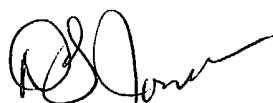
COMMENTS/NOTES

8. It should be noted that no prior art has been cited against the instant invention. However, Applicant MUST address and overcome the double patenting and 112 rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a composition and uses thereof wherein the composition comprises a metal support surface and a conjugate that is releasable bound to the support surface and comprises a ligand and a targeting molecule. This is true for the aspects of the instant invention which meet the written description requirement.
9. The new grounds of rejection serve to clarify exactly what is being claimed.
10. It is respectfully suggested that Applicant replace ^{99m}Tc with ^{99m}Tc in claim 34.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
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June 10, 2004